

**Remarks/Argument**

By the present amendment, claims 1 and 22-23 have been amended, and claim 38 has been added. Support for amended claims 1 and 22-23, as well as new claim 38 can be found at at least p. 11, lines 3-25, and p. 13, line 28 to p. 14, line 1 of the present application.

Below is a discussion of the February 23, 2010 telephone conversation with Examiner Sgagias, the 35 U.S.C. §112, first paragraph, rejection of claims 1-2, 5, 7, 21-23 and 37, and the patentability of new claim 38.

**1. February 23, 2010 telephone conversation.**

Applicants wish to memorialize the February 23, 2010 telephone conversation with Examiner Sgagias in which Applicants' proposed claim amendments were discussed. Examiner Sgagias informed Applicants that she could not say whether the proposed claim amendments would overcome the outstanding 35 U.S.C. §112, first paragraph, rejection without further searching. Examiner Sgagias suggested that Applicants file an After File Amendment including the proposed claim amendments. Examiner Sgagias agreed that she would review the After Final Amendment and then inform Applicants as to whether she would enter the After Final Amendment or require Applicants to file an RCE.

**2. 35 U.S.C. §112, first paragraph, rejection of claims 1-2, 5, 7, 21-23, and 37**

Claims 1-2, 5, 7, 21-23, and 37 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action argues the claims embrace an enormous number of integrin-receptor binding

fragments constituting a claimed genus. Thus, the Office Action argues, the claims embrace a claimed genus that encompasses integrin-receptor binding fragments yet to be discovered.

By the present amendment, claims 1 and 23 have been amended to recite "vitronectin (VN) or an  $\alpha_v$  integrin-receptor binding fragment thereof that does not comprise a heparin binding domain (HBD)." Applicants respectively submit that the amendments to claims 1 and 23 satisfy the requirements of 35 U.S.C. §112, first paragraph, because the present specification sufficiently describes the structure or functional nature of VN or an  $\alpha_v$  integrin-receptor binding fragment thereof that does not comprise a HBD. For example, the present application discloses that the VN fragments may be characterized as: (i) having at least an  $\alpha_v$  integrin-receptor binding region; and (ii) lacking a HBD (*see* p. 11, lines 3-25). With respect to the  $\alpha_v$  integrin-receptor binding (or RGD) region of VN, this has been studied in numerous papers published prior to the priority date of the present invention. In fact, this domain has been mapped as far as the specific residues of VN that activate signaling pathways (*see, e.g.,* Seger *et al., J Biol Chem.*, 273(38):24805-24813, 1998; attached hereto). Additionally, the HBD of VN has been previously identified as the C-terminal region of mature VN (*i.e.*, amino acid residues 347-459).

The subject matter of amended claims 1 and 23 is also fully supported by the disclosure of International Application No. PCT/AU2004/000117 ("the '117 application"), which is incorporated by reference into the present application (*see* p. 11, line 9). For example, the '117 application discloses a number of different integrin-receptor binding VN fragments (*see, e.g.,* p. 13, line 17 to p. 15, line 20).

Additionally, the '117 application discloses VN fragments that do not comprise the HBD of mature VN (*i.e.*, amino acid residues 347-459) (*see* p. 35, lines 19-23 and Fig. 8), as well as specific examples of biologically active integrin receptor-binding VN fragments that lack the HBD (*see* p. 15, lines 7-8 and Fig. 14).

Accordingly, Applicants respectively submit that the subject matter of amended claims 1 and 23 is described with sufficient particularity such that one of ordinary skill in the art would recognize that Applicants were in possession of the claimed the subject matter at the time of invention, and request that the 35 U.S.C. §112, first paragraph, rejection of claims 1 and 23 be withdrawn. Additionally, Applicants respectively request that the 35 U.S.C. §112, first paragraph, rejection of claims 2, 5, 7 and 21-22, which depend directly from claim 1, be withdrawn.

**3. Patentability of new claim 38.**

By the present amendment, Applicants have added claim 38. New claim 38 depends directly from claim 1 and recites the further feature that the  $\alpha_v$  integrin-receptor binding fragment comprises amino acid residues 1-52 of mature VN.

Applicants respectively submit that new claim 38 satisfies the requirements of 35 U.S.C. §112, first paragraph, because one skilled in the art at the time of the present invention would have understood that the Applicants were in possession of an  $\alpha_v$  integrin-receptor binding fragment comprising amino acid residues 1-52 of mature VN. Support for new claim 38 can be found at at least p. 11, lines 15-25, and p. 13, line 28 to p. 14, line 1 of the present application. Additionally, one skilled in the art would appreciate that the claims recite VN fragments that are: (i) capable

of binding to an  $\alpha$ , integrin-receptor (*i.e.*, include at least an RGD) and (ii) lack the HBD. From this, the skilled artisan would understand that these features inevitably lead to a VN fragment that comprises amino acid residues 1-52 of mature VN.

Accordingly, Applicants respectively submit that new claim 38 satisfies the requirements of 35 U.S.C. §112, first paragraph, and allowance of new claim 38 is requested.

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Respectfully submitted,

/Richard S. Wesorick/

Richard S. Wesorick  
Reg. No. 40,871

TAROLLI, SUNDHEIM, COVELL,  
& TUMMINO L.L.P.  
1300 East Ninth Street, Suite 1700  
Cleveland, Ohio 44114  
Phone: (216) 621-2234  
Fax: (216) 621-4072  
Customer No.: 26,294